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NIXON PEABODY

NO. 6345 P. 10

Docket No. 741890-20
#8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Martin CALDWELL et al.

Serial No. 09/936,841

Filed: September 18, 2000

For: A SURGICAL ACCESS DEVICE

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) Group Art Unit: 3731

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) Examiner: M. Milano

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April Campbell
April Campbell

PETITION TO MAKE SPECIAL
UNDER 37 C.F.R. 1.102(c) AND MPEP 708.02(VIII)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. 1.102(c) and MPEP 708.02(VIII), Applicants request that the above identified application be granted special status under Category VIII of MPEP 708.02. In support of this request, applicant states or submits herewith the following:

1. The petition fee of \$130 as set forth in 37 CFR 1.17(i) and requests that any overpayment be credited to and any deficiency be charged to Deposit Account No. 19-2380 (741890-20);

2. Applicants respectfully submit that claims 1-12 (i.e., claims 1-10 are present in "Amended Sheet" form from the international preliminary examination stage, the Applicant have provided copy with the National Stage 371 application papers, and claims 11 and 12 are presented in the form of a preliminary amendment filed July 17, 2002) are

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directed to a single invention but, if the Office determines that all the presented claims are not obviously directed to a single invention, the Applicants will make an election without traverse;

3. A pre-examination search was made by the European Patent Office in connection with priority application PCT/IE00/00033 and a copy of the International Search Report was submitted with the Application papers which shows the field of search. A copy of each reference cited on the International Search Report is also present in the file as indicated by the Notice of Acceptance mailed January 27, 2003; further, the Applicants had a search performed of US classes/subclasses as follows:

<u>Class</u>	<u>Subclass</u>
128	846, 850, 852 (US and Foreign)
600	208, 207, 235 (US and Foreign)
602	60 (US and Foreign)
604	167.03, 256, 264 (US and Foreign)
606	185, 213, 215 (US and Foreign)

4. Applicants submit one copy of each reference most closely related to the subject matter of the claims, either attached hereto, submitted with the IDS of July 17, 2002 or as part of the International Search Report;

5. Applicant offers the following detailed discussion of the references determined to be most closely related to the subject matter of the claims, pointing out how the claimed subject matter is patentable over the reference.

Initially, it should be noted that the inventive combination of features of the claims, i.e., independent claims 1, 11 and 12, is the body cavity retraction means (formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each such that operation of the proximal ring shortens the length of the sleeve to retract the cavity opening) and the sealing means (mounted on either the sleeve, the distal ring of the engagement means or the proximal ring of the fixing means) to prevent substantial leakage of gas from a body cavity.

The prior art can be generally separated into three categories:

- A. Cavity retractors only
- B. Cavity sealers only
- C. Cavity retractors and sealers

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For the category A. (cavity retractors only) the following documents are most closely related to the subject matter of the claims:

Crook (USP 5,649,550) which teaches (Figures 2, 3, 5A, 5B, elements 12, 16, 18; column 3, lines 19-42; column 4, lines 15-49) a distal ring (16) and proximal ring (18) having connected thereto an adjustable length sleeve (12) wherein the apparatus functions to retract the edges of a cavity opening of a patient by rolling downward the proximal ring (18) to draw the sleeve (12) tight and widen the cavity opening.

Crook (USP 5,524, 644) which teaches (Figures 2-4, elements 12, 18, 20; column 3, line 28, to column 4, line 20; column 5, lines 1-21) a distal ring (20) and proximal ring (18) having connected thereto an adjustable length sleeve (12) wherein the apparatus functions to retract the edges of a cavity opening of a patient by rolling downward the proximal ring (18) to draw the sleeve (12) tight and widen the cavity opening.

Crook (USP 6,382,211), like Crook '550 above, teaches (Figures 2, 3, 5A, 5B, elements 12, 16, 18; column 3, line 58, to column 4, line 33; column 5, lines 31-45) a distal ring (20) and proximal ring (18) having connected thereto an adjustable length sleeve (12) wherein the apparatus functions to retract the edges of a cavity opening of a patient by rolling downward the proximal ring (18) to draw the sleeve (12) tight and widen the cavity opening.

Bonadio et al (US Appl. Pub. 2001/0037053) which teaches (Figures 3-5, elements 10, 11, 20, 21; paragraphs [0083]-[0084]; Figures 14, 15a, 15b, 16, elements 82, 83, 86; paragraph [0095]) two general apparatus for cavity retraction wherein the first apparatus (Figures 3-5) includes a distal ring (10) and two proximal rings (20, 21) having connected thereto an adjustable length sleeve (11) which functions to retract the edges of a cavity opening of a patient by rotating a first proximal ring (20) relative to a second proximal ring (21) to draw the sleeve (11) tightly to the body cavity and widen the cavity opening. The

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second general apparatus (Figures 14, 15a, 15b, 16) includes a distal ring (83) and a proximal ring (84) having connected thereto both ends of adjustable length straps (86) which function to retract the edges of a cavity opening of a patient by drawing the strap ends (Figure 15) upward relative to the proximal ring (84) to draw the strap tight to the body cavity and widen the cavity opening.

Harrower (USP 3,347,227) which teaches (Figures 1-6, elements 12, 14, 16; column 1, line 60, to column 2, line 55) a distal ring (14) and proximal ring (12) having connected thereto a sleeve (16) wherein the apparatus functions to retract the edges of a cavity opening of a patient by squeezing together the sides of the distal ring (14), inserting the distal ring (14) into the body cavity and allowing the distal ring (14) to expand to its normal form to bring the sleeve (16), distal ring (14) and proximal ring (12) into close contact with the cavity opening to hold the cavity open.

What is not taught or suggested by each of these cavity retractor only references is a sealing means (mounted on either the sleeve, the distal ring of the engagement means or the proximal ring of the fixing means) to prevent substantial leakage of gas from a body cavity. Therefore, the presently claimed invention is distinguished from each of the cavity retractor only documents.

For the category B. (cavity sealers only) the following documents are most closely related to the subject matter of the claims:

Golub et al (USP 5,514,133) teach (Figures 1-3, 4, 5, elements 12, 14, 16, 56, 62, 64; column 3, line 61, to column 5, lines 14) a distal ring (14) and proximal ring (12) having connected thereto a collapsible sleeve (16). Further, the patentees teach a sealing member (56) having valve seals (62, 64) attached to thereto and secured to the proximal ring (12). The apparatus functions to seal the cavity by drawing the distal ring (14) and proximal ring (12) together using string adjustments members (24) which, when drawn,

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pull the two rings together (Figures 3, 4) thereby compressing the rings to the inner and outer cavity surfaces while the compressed sleeve (16) is out of contact with the cavity walls. The sealing member (56) thereby seals the cavity preventing the escape of gas within the cavity.

Brinkerhoff et al (USP 5,366,478) teach (Figures 1-3, elements 11, 19, 20; column 4, lines 14-60) a distal ring (20) and proximal ring (19) placed inside a collapsible and expandable tubular sleeve (11). The apparatus functions to seal the cavity by placing the distal ring (20) of the deflated device (10) into cavity opening and inflating (Figure 2) the tubular sleeve (11) only sufficiently for the inner lumen portion (21) of the tubular sleeve (11) to seal the cavity opening. The patentees set forth no discussion of a retraction function of the sealing device (10).

Bonadio et al (WO/ 95/07056) which teaches (Figures 3-7, 9, elements 2, 21, 22, 61, 62, 63; page 7, line 20, to page 9, line 4; page 9, line 27, to page 10, line 4) sealing a cavity opening against the escape of gas from the cavity by an apparatus which includes a sealing diaphragm (Figure 9) having a proximal ring (61), a distal ring (63) and a tubular sleeve (62) attached to each in which the preformed assembly is placed into the cavity opening (Figure 9) to seal the cavity opening. The apparatus further includes a second tubular sleeve (2) attached to the sealing diaphragm at one end and attached to a first sealing ring (21) at another end. The first seal ring (21) in turn is connected to a second sealing ring (22) via another tubular sleeve (23) which effects sealing against the escape of gas by bringing the first ring (21) into engagement with the second ring (22) when an arm is inserted and locking the two rings together with locking means (27, 28). It is noted that Bonadio et al set forth no discussion of a retraction function of the sealing diaphragm.

Williamson, IV (USP 5,545,179) which teaches (Figures 1, 3, 5, 6, elements 22, 23, 26, 27, 29; column 4, line 18, to column 5, line 8) an apparatus for sealing a cavity opening

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from the escape of gas including a first rigid ring (29) having a first fixed dimension opening (31), a second rigid ring (27) having a fixed dimension opening (44) equal to the first fixed dimension opening and an elastomeric, inflatable tubular sleeve (26). The sealing of the cavity opening is effected by assembling the tubular sleeve (26) with the interfit first (27) and second (29) rings to define an inflatable bladder (Figure 6). Then the bladder portion (23) is inserted into the opening with the interfit rings (27, 29) adjacent the external surface of the cavity opening and the bladder portion is inflated sufficiently to bring the walls (34) of the central channel of the bladder together (Figure 3). The patentees set forth no discussion of the bladder performing any retraction function and such would be contrary to the sealing function proscribed since the first (29) and second (27) rings have fixed inner dimensions.

What is not taught or suggested by each of these cavity sealing only references is the body cavity retraction means formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each. Therefore, the presently claimed invention is distinguished from each of the cavity sealing only reference documents.

For the category C. (cavity retractors and sealers) the following documents are most closely related to the subject matter of the claims:

Beane et al (USP 5,906,577) which teaches (Figures 1, 2C-2E, 3, elements 10, 12, 14, 62, 64, 66, 68, 69; column 6, lines 24-68) a combination cavity retractor including a distal ring (64), an inflatable proximal ring (68, 69) and tubular sleeve (66) connected therebetween, and a cavity sealing port (62) including self-sealing valve (14) attached, via an inflatable skirt (66), to the upper portion of the tubular sleeve (66). The operation of the cavity retractor includes placing the distal ring (64) inside the cavity opening, and then inflating the proximal ring (68, 69) to elevate and radially expand the sleeve (66) to seal to the cavity opening and retract the tissue of the opening. Meanwhile, the self-sealing valve

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(14), upon inflation of the cavity, seals the cavity from the escape of gas. The teachings of Beane et al do not appreciate or suggest a body cavity retraction means formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each other such that operation of the proximal ring shortens the length of the sleeve to retract the cavity opening, and further, Beane et al do not teach or suggest a sealing means mounted on either the distal ring of the engagement means or the proximal ring of the fixing means to prevent substantial leakage of gas from a body cavity.

Beane et al (USP 6,440,063), like Beane et al '577, teaches (Figures 1, 6; column 1, line 45, to column 2, line 8; column 9, lines 31-48) a combination cavity retractor including a distal ring (64), an inflatable proximal ring (68, 69) and tubular sleeve (66) connected therebetween, and a cavity sealing port (76) attached to the upper portion of the tubular sleeve (66). The operation of the cavity sealing port is via a relative twisting rotation of the two rings (70, 72) which results in elastic sleeve (74) becoming constricted (Figure 6B) thereby sealing the cavity from the escape of gas. These teachings of Beane et al '063 do not appreciate or suggest a body cavity retraction means formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each other such that operation of the proximal ring shortens the length of the sleeve to retract the cavity opening. Further, Beane et al '063 do not teach or suggest a sealing means mounted on either the distal ring of the engagement means or the proximal ring of the fixing means to prevent substantial leakage of gas from a body cavity.

Shimomura et al (USP 6,077,288) teaches (Figures 8A, 8B; column 7, line 51, to column 8, line 36) a combination cavity retractor including a distal ring (116), an inflatable proximal ring (112) and tubular sleeve (111) connected therebetween, and a cavity sealing port (100D) attached to the upper portion of the tubular sleeve (111). The operation of the

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cavity sealing port is via a relative movement of the two rings (11, 12) towards each other which results in elastic sleeve (13a) becoming narrowed (Figure 8B) thereby sealing the cavity from the escape of gas. These teachings of Shimomura et al do not appreciate or suggest a body cavity retraction means formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each other such that operation of the proximal ring shortens the length of the sleeve to retract the cavity opening. Further, Shimomura et al do not teach or suggest a sealing means mounted on either the distal ring of the engagement means or the proximal ring of the fixing means to prevent substantial leakage of gas from a body cavity.

Leahy et al (USP 5,640,977) teaches (Figures 2, 3, elements 13, 14, 16, 20, 32; column 3, line 36, to column 4, line 31) a combination cavity retractor including a distal ring (14), a proximal ring (16) and tubular sleeve (13) connected therebetween, and a cavity sealing port (20, 32) attached, via an external tubular sleeve (18a, 18b) to the upper portion of the tubular sleeve (13). The operation of the cavity retractor occurs as a result of the expansion of the distal (14) and proximal (16) rings; while operation of the cavity sealing port is via a duckbill check valve (32) and an inflatable cuff (20) each of which are attached to an external tubular sleeve (18a, 18b) thereby sealing the cavity from the escape of gas. These teachings of Leahy et al do not appreciate or suggest a body cavity retraction means formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each other such that operation of the proximal ring shortens the length of the sleeve to retract the cavity opening. Further, Leahy et al do not teach or suggest a sealing means mounted on either the tubular sleeve, the distal ring of the engagement means or the proximal ring of the fixing means to prevent substantial leakage of gas from a body cavity.

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Gerhart et al (USP 6,149,642) teaches (Figure 1, elements 12, 14; column 2, line 62, to column 3, line 12) a combination cavity retractor, like that of the Crook references above including a distal ring, a proximal ring and tubular sleeve (13) connected therebetween, and an entirely separate cavity sealing port (14) which envelops the cavity retractor (12) but is otherwise unassociated with the cavity sealing port (14). These teachings of Gerhart et al do not appreciate or suggest a body cavity retraction means (formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each other) where a cavity sealing means is mounted on either the tubular sleeve, the distal ring of the engagement means or the proximal ring of the fixing means to prevent substantial leakage of gas from a body cavity.

Kaji (USP 6,033,426) which teaches (Figures 1, 2A, 2B, 7A, 7B, 13, 17, 18, elements 2, 3, 6, 40, 44; column 6, lines 12-68; column 7, lines 3-24; column 11, lines 31-63) a combination cavity retractor including a distal ring (6), an inflatable proximal ring (40) and tubular sleeve (3) connected therebetween, and a cavity sealing port (2) including self-sealing valve (10) attached to the lower portion of the tubular sleeve (66) to prevent escape of gas from the cavity when an arm is not inserted (Figure 2A). The operation of the cavity retractor includes placing the distal ring (6) inside the cavity opening, and then inflating the proximal ring (40) to elevate and radially expand the sleeve (3) to seal to the cavity opening and retract the tissue of the opening (column 3, lines 4-5). Meanwhile, the self-sealing valve (10), upon inflation of the cavity, seals the cavity from the escape of gas when an arm is not inserted. The teachings of Kaji do not appreciate or suggest a body cavity retraction means formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each other such that operation of the proximal ring shortens the length of the sleeve to retract the cavity opening, and further, Kaji do not teach or suggest a sealing means mounted on either

the distal ring of the engagement means or the proximal ring of the fixing means to prevent substantial leakage of gas from a body cavity.

In summary, what is not taught or suggested by each of these combination cavity retractor and sealing apparatus documents is the body cavity retraction means formed by an engagement means including a distal ring, a fixing means including a proximal ring and an adjustable length sleeve connected to each connected to a sealing means (mounted on either the distal ring of the engagement means or the proximal ring of the fixing means) to prevent substantial leakage of gas from a body cavity. Therefore, the presently claimed invention is distinguished from each of the combination cavity retractor and sealing documents.

In view of the foregoing, Applicants respectfully request that special status be granted to the above identified application.

Respectfully submitted,



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